REMARKS

Office Action

In the Office Action mailed February 20, 2007, the Examiner rejected claims 1-3, 6-11, and 15-20 as being anticipated under 35 U.S.C. 102(e) by Lang et al., U.S. Publ. No. 2004/0138754 (hereinafter "Lang"). Claims 4-5 and 12 were rejected as being obvious under 35 U.S.C. 103(a) over Lang in view of "official notice." No official action was stated regarding claims 13 and 14. For reasons stated in more detail below, Applicant respectfully disagrees with the Examiner's reading and interpretation of Lang and submits that pending claims 1-20 are patentable over all references of record, either alone or in combination.

Claims 1-2

Claim 1 is a method for designing a surgical guide for a joint replacement prosthesis. It requires generation of a bone surface image, generation of a surgical guide image from the bone surface image and a prosthetic image imposed on the bone surface image, and generation of control data from the generated surgical guide image. The control data is used to operate a machine to fabricate a surgical guide. With the exception of the generation of the bone surface image, the Examiner has failed to identify any portion of Lang that discloses the limitations of claim 1.

Nowhere in Lang is there a teaching or a suggestion to generate a surgical guide image from a bone surface image and an image of a prosthetic imposed on the bone surface image. Instead, Lang teaches the generation of *measurements* from a bone surface image and the use of those measurements for the selection or fabrication of prosthetics. *Lang*, ¶s 28-29, 78-79. Using a model representation of a joint, *a practitioner* may design a joint prosthetic. Lang actually teaches away from Applicant's invention, which requires the generation of the control data from the generated surgical guide image, which is generated from the bone surface image and the prosthetic image imposed on the bone surface image. Lang does not teach or suggest the generation of control data, but rather relies on the practitioner in some unidentified offline procedure to design the prosthetic as well as design any tool or guide to be used with the prosthetic.

With regard to guides, Lang teaches only that guides may be used that partially or substantially conform to the implantation site or joint cavity. *Lang*, ¶ 36. Lang teaches that guides may be constructed using object coordinates obtained from images of bones alone. *Lang*, ¶s 235-244. Lang also teaches that object coordinates of bone surfaces alone may be used to position guides on frames. *Lang*, ¶ 247. Lang teaches that re-useable tools may be constructed by transferring object coordinates from images of bones alone to the re-useable tools. *Lang*, ¶ 249. However, Lang does not teach or even suggest that the guide be fabricated from material using control data that has been generated from a surgical guide image generated from a bone surface image and a prosthetic image imposed on the bone surface image. That is, the tools produced by the method taught by Lang do not take into account the prosthetic with which the tool is to be used. Applicant's invention on the other hand, fabricates a tool with reference to the prosthetic and generates control data from an image that includes the bone and the prosthetic for the fabrication of the tool. Thus, Lang does not teach each and every limitation of claim 1 and cannot anticipate the claim. Therefore, Lang cannot anticipate the claim and this ground of rejection should be withdrawn.

Claim 2 depends from claim 1 and, therefore, contains the limitations of claim 1. Consequently, claim 2 is patentable for the reasons discussed above with respect to claim 1.

Claim 3

Claim 3 depends from claim 1 and, therefore, contains the limitations of claim 1. Consequently, claim 3 is patentable for the reasons discussed above with respect to claim 1. Moreover, claim 3 requires that the generation of the surgical guide image include the integration of at least one marker slot in the surgical guide image. Lang has no teaching or suggestion that one or more marker slots be included in a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface. For at least these reasons, claim 3 is patentable over all references of record, either alone or in combination.

Claim 4

Claim 4 depends from claim 1 and, therefore, contains the limitations of claim 1. Consequently, claim 4 is patentable for the reasons discussed above with respect to claim 1. Moreover, claim 4 requires that the control data generated from the surgical guide image be used to control a laser for the selective crystallization of a resin to form a surgical guide that corresponds to the surgical guide image. Lang has no teaching or suggestion that control data generated from a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface be used to control operation of a laser. The Examiner admits the absence of this limitation, but states that "it is well known in the art of rapid prototyping to use laser sintering of polymer resins or mechanical milling to construct the (sic) 3-D representation." Official notice requires that an official take notice of a commonly accepted fact without requiring authentication of the source. For example, an official may take notice that the sun rose at a particular geographical location at certain time on a specific date from an almanac. The almanac is considered a reliable source of commonly known information. In this case, however, the Examiner has stated a "fact" without reference to any source for the fact or the knowledge being commonly accepted at a particular time. Such action does not properly qualify as "official notice" and the obviousness ground of rejection of claim 4 should be withdrawn.

For at least these reasons, claim 4 is patentable over all references of record, either alone or in combination.

Claim 5

Claim 5 depends from claim 1 and, therefore, contains the limitations of claim 1. Consequently, claim 5 is patentable for the reasons discussed above with respect to claim 1. Moreover, claim 5 requires that the control data generated from the surgical guide image be used to control a machine tool for the selective cutting of a solid material to form a surgical guide that corresponds to the surgical guide image. Lang has no teaching or suggestion that control data generated from a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface be used to control operation of a machine tool. The Examiner admits the absence of this limitation, but states that "it is well known in the art of rapid prototyping to use laser sintering of polymer resins or mechanical

milling to construct the (sic) 3-D representation." Official notice requires that an official take notice of a commonly accepted fact without requiring authentication of the source. As noted above with claim 4, the Examiner, in this case, has stated a "fact" without reference to any support for the fact or the knowledge being commonly accepted at a particular time. Such action does not properly qualify as "official notice" and the obviousness ground of rejection of claim 5 should be withdrawn.

For at least these reasons, claim 5 is patentable over all references of record, either alone or in combination.

Claim 6

Claim 6 depends from claim 1 and, therefore, contains the limitations of claim 1. Consequently, claim 6 is patentable for the reasons discussed above with respect to claim 1. Moreover, claim 6 requires that stereolithography data be generated from the surgical guide image. Lang has no teaching or suggestion that stereolithography data be generated from a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface. For at least these reasons, claim 6 is patentable over all references of record, either alone or in combination.

Claim 7

Claim 7 depends from claim 1 and, therefore, contains the limitations of claim 1. Consequently, claim 7 is patentable for the reasons discussed above with respect to claim 1. Moreover, claim 7 requires that machine tool control data be generated from the surgical guide image. Lang has no teaching or suggestion that machine tool control data generated from a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface be used to control operation of a laser. For at least these reasons, claim 7 is patentable over all references of record, either alone or in combination.

Claims 8-9

Claim 8 is directed to a system for designing a surgical guide for a joint replacement prosthesis. It requires a bone surface image generator, a surgical guide image generator that

generates a surgical guide image from the bone surface image and a prosthetic image imposed on the bone surface image, and a surgical guide image converter for generating control data from the generated surgical guide image. The control data is used to operate a machine to fabricate a surgical guide. With the exception of a bone surface image generator, the Examiner has failed to identify any portion of Lang that discloses the limitations of claim 8.

Nowhere in Lang is there a teaching or a suggestion of a surgical guide image generator that generates a surgical guide image from a bone surface image and an image of a prosthetic imposed on the bone surface image. Instead, Lang teaches the generation of *measurements* from a bone surface image and the use of those measurements for the selection or fabrication of prosthetics. *Lang*, ¶s 28-29, 78-79. Using a model representation of a joint, *a practitioner* may design a joint prosthetic. Lang actually teaches away from Applicant's invention, which requires the generation of the control data from the surgical guide image generated by the surgical guide image generator, which uses the bone surface image *and* the prosthetic image imposed on the bone surface image. Lang does not teach or suggest the generation of control data, but rather relies on the practitioner for the design of the prosthetic as well as the design of any tool or guide to be used with the prosthetic. With regard to guides, Lang teaches only that guides may be used that partially or substantially conform to the implantation site or joint cavity. *Lang*, ¶ 36. Lang does not teach or even suggest that the guide be fabricated from material using control data that has been generated from a surgical guide image generated from a bone surface image and a prosthetic image imposed on the bone surface image. Without an express teaching of each and every limitation of a claim, a reference cannot anticipate a claim.

In the Office Action, the Examiner has referenced some generalities of Lang regarding its field of invention and and the use of guides in implantation surgeries. These general comments of Lang do not teach each and every limitation of claim 8. Therefore, Lang cannot anticipate the claim and this ground of rejection should be withdrawn.

Claim 9 depends from claim 8 and, therefore, contains the limitations of claim 8. Consequently, claim 9 is patentable for the reasons discussed above with respect to claim 8.

Claim 10

Claim 10 depends from claim 8 and, therefore, contains the limitations of claim 8. Consequently, claim 10 is patentable for the reasons discussed above with respect to claim 8. Moreover, claim 10 requires that the surgical guide image generator integrate at least one marker slot in the surgical guide image. Lang has no teaching or suggestion that one or more marker slots be included in a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface. For at least these reasons, claim 10 is patentable over all references of record, either alone or in combination.

Claim 11

Claim 11 depends from claim 8 and, therefore, contains the limitations of claim 8. Consequently, claim 11 is patentable for the reasons discussed above with respect to claim 8. Moreover, claim 11 requires that the control data generator generate control data that is used to control a laser for the selective crystallization of a resin to form a surgical guide that corresponds to the surgical guide image. Lang has no teaching or suggestion that control data generated from a surgical guide image that has been generated from an image of a bone surface and a prosthetic imposed on the bone surface be used to control operation of a laser.

Although claim 11 is similar to claim 4, the Examiner has asserted that claim 11 is anticipated by Lang. In light of the Examiner's admission with respect to claim 4 that "Lang et al. does not teach of laser sintering or milling a surgical guide," the Applicant concludes that the Examiner has admitted that claim 11 is not anticipated by Lang.

Assuming the Examiner meant to reject claim 11 as being obvious as argued with respect to claim 4, the Examiner would have to rely on the official notice presented above with respect to that claim. Such reliance does not properly support a section 103 ground of rejection as the Examiner's assertion that "it is well known in the art of rapid prototyping to use laser sintering of polymer resins or mechanical milling to construct the (sic) 3-D representation, " does not conform to the requirements for official notice. Official notice requires that an official take notice of a commonly accepted fact without requiring authentication of the source. In this case, however, the Examiner has stated a "fact" without reference to any

support for the fact or the knowledge being commonly accepted at a particular time. Such action does not properly qualify as "official notice," because the Examiner is not *noticing* a well-known fact, but rather is stating something as being factual without notice of any source attesting to the "fact." Therefore, if the Examiner meant to reject claim 11 as being obvious, the obviousness ground of rejection of claim 11 should be withdrawn.

Claim 12

Claim 12 depends from claim 8 and, therefore, contains the limitations of claim 8. Consequently, claim 12 is patentable for the reasons discussed above with respect to claim 8. Moreover, claim 12 requires that the control data generator generate computerized numerical control data for control of a cutting tool for the selective cutting of a solid material to form a surgical guide that corresponds to the surgical guide image. Lang has no teaching or suggestion of a control data generator that generates computerized numerical control data from a surgical guide image generated from an image of a bone surface and an image of a prosthetic imposed on the bone surface. The Examiner admits the absence of Lang teaching about the milling of a surgical guide, but states that "it is well known in the art of rapid prototyping to use laser sintering of polymer resins or mechanical milling to construct the (sic) 3-D representation." Official notice requires that an official take notice of a commonly accepted fact without requiring authentication of the source. As noted above with claims 4-5 and 11, the Examiner, in this case, has stated a "fact" without reference to any support for the fact or the knowledge that is being asserted as being commonly accepted at a particular time. Such action does not properly qualify as "official notice" and the obviousness ground of rejection of claim 12 should be withdrawn.

For at least these reasons, claim 12 is patentable over all references of record, either alone or in combination.

Claims 13-14

Claims 13 and 14 were not addressed in the Office Action. These claims depend from claim 8, and therefore, include the limitations of claim 8. Consequently, they are patentable for reasons similar to those discussed above with claim 8. Additionally, claim 13 requires that the surgical guide image generator generate the surgical guide image from an acetabulum bone

surface image and an acetabular cup image. Likewise, claim 14 requires that the surgical guide image generator generate the surgical guide image from a femur bone surface image and a femoral stem image. Because Lang does not teach or suggest the generation of a surgical guide image from either of these bone surface images and the images of their corresponding prosthesis, these claims are also patentable over all references of record, either alone or in combination.

Claim 15

Claim 15 is directed to a system that aids a surgeon during a joint replacement operation. The system includes a patient bone data repository for storing three dimensional data of a patient's bone, a reference pointer for providing positional data of a surgical site, a registration module for receiving the positional data and correlating the positional data of the surgical site obtained from the reference pointer to the three dimensional data for the bone stored in the patient bone data repository, and an image generator for generating an image of the patient's bone from the data stored in the patient bone data repository with an image of a prosthetic implant imposed on the generated image of the patient's bone. The Examiner is correct that Lang discloses a titanium FARO arm, but there is no teaching or suggestion that the arm is used as a reference pointer for providing positional data of a surgical site or that it is used with an image generator that generates an image of a patient's bone with an image of a prosthetic implant imposed on the image of the bone. Without such a teaching Lang cannot anticipate claim 15. Therefore, claim 15 is patentable over all references of record either alone or in combination.

Claim 17

Claim 17 depends from claim 15 and is patentable for the reasons discussed above with respect to that claim. Additionally, claim 17 requires the image generator to generate the image of the patient's bone with the prosthetic imposed on it in an orientation that corresponds to the angular orientation of the reference pointer with respect to a position on the bone. The Examiner is correct that Lang discloses a titanium FARO arm, but there is no teaching or suggestion in Lang that an image generator generates the image set forth in claim 15 with the angular orientation of the reference pointer with respect to a position on the

bone. Without such a teaching Lang cannot anticipate claim 17. Therefore, claim 17 is patentable over all references of record either alone or in combination.

Claim 18

Claim 18 depends from claim 15 and is patentable for the reasons discussed above with respect to that claim. Additionally, claim 18 requires the reference pointer to be an articulating arm with positional gyros mounted at pivotal joints of the articulating arm. The Examiner is correct that Lang discloses a titanium FARO arm, but there is no teaching or suggestion in Lang that the titanium FARO arm has positional gyros at pivotal joints and that the reference pointer be used in the system as described in claim 15. Without such a teaching Lang cannot anticipate claim 18. Therefore, claim 18 is patentable over all references of record either alone or in combination.

Claim 19

Claim 19 depends from claim 15 and is patentable for the reasons discussed above with respect to that claim. Additionally, claim 19 requires the reference pointer to communicate wirelessly with the registration module. The Examiner is correct that Lang discloses a titanium FARO arm, but there is no teaching or suggestion in Lang that the titanium FARO arm wirelessly communicate with a registration module. Without such a teaching Lang cannot anticipate claim 19. Therefore, claim 19 is patentable over all references of record either alone or in combination.

Claim 20

Claim 20 depends from claim 15 and is patentable for the reasons discussed above with respect to that claim. Additionally, claim 20 requires the image generator to generate an image of an acetabular cup on an image of a patient's acetabulum bone. Lang does not disclose an image generator that generates an image of a patient's acetabulum bone with an acetabular cup imposed on it. Without such a teaching Lang cannot anticipate claim 20. Therefore, claim 20 is patentable over all references of record either alone or in combination.

Conclusion

For the reasons set forth above, all pending claims are patentable over all references of record, either alone or in combination. Reexamination and allowance of all pending claims are earnestly solicited.

Respectfully submitted,
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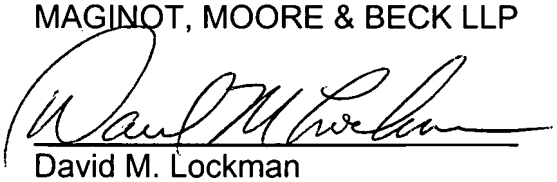

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